

Claims

We claim:

1. A method for detecting a target analyte/biomarker comprising:
 - (a) mixing *ex vivo* a nanostructure-based assembly with a sample of bodily fluid;
and
 - (b) analyzing the mixture of nanostructure-based assembly and bodily fluid sample with sensor technology to determine the presence of the target analyte/biomarker.
2. The method according to claim 1, wherein the nanostructure-based assembly comprises at least one nanotube comprising a hollow interior, a first end, a second end, surrogate marker located within the hollow interior, and an end-cap, wherein the first end is open and the second end is closed, the first end being blocked with the end-cap to prevent the release of the surrogate marker, wherein a means for detecting the target analyte/biomarker is attached to the end-cap; wherein when the means for detecting the target analyte/biomarker is in the presence of the target analyte/biomarker, the end-cap is displaced from the first end to release the surrogate marker.
3. The method according to claim 2, wherein the means for detecting to the target analyte/biomarker is selected from the group consisting of aptamers, antibodies, proteins, and receptor ligands.
4. The method according to claim 3, wherein the aptamer is capable of binding to the target analyte/biomarker selected from the group consisting of α II-spectrin breakdown products and protease-specific spectrin breakdown products.

5. The method according to claim 1, wherein the target analyte/biomarker is a nucleic acid, a protein, an illicit drug, an explosive, a toxin, a pharmaceutical, a carcinogen, a poison, an allergen, or an infectious agent.

6. The method according to claim 1, wherein the target analyte/biomarker is selected from the group consisting of acetaldehyde, acetone, ammonia, CO, chloroform, dichlorobenzene, diethylamine, hydrogen, isoprene, methanethiol, methylethylketone, O-toluidine, pentane sulfides and sulfides, H₂S, MES, and Me₂S.

7. The method according to claim 1, wherein the bodily fluid sample is selected from the group consisting of: exhaled breath, blood, urine, bile, sweat, feces, semen, saliva, mucus, and cerebral spinal fluid.

8. The method according to claim 1, wherein the sensor technology is selected from the group consisting of surface-acoustic-wave sensors; fluid sensor technology; semiconductive gas sensors, mass spectrometers; IR, UV, visible and fluorescence spectrophotometers; conductive-polymer gas-sensors; aptamer biosensors; and amplifying fluorescent polymer sensors.

9. The method according to claim 1, wherein the sensor technology comprises:

- (a) a surface-acoustic wave (SAW) sensor capable of detecting the presence of a surrogate marker in a sample of bodily fluid, wherein the SAW sensor responds to the surrogate marker by a shift in the resonant frequency;
 - (b) an oscillator circuit having the SAW sensor as an active feedback element;
 - (c) a frequency counter in communication with said oscillator circuit to measure oscillation frequency which corresponds to resonant frequency of the SAW sensor;
- and

- (d) a processor for comparing the oscillation frequency with a previously measured oscillation frequency of the surrogate marker and determining presence and concentration of the surrogate marker therefrom.

10. The method according to claim 1, wherein the sensor technology comprises:

- (a) a sensor having an array of polymers capable of detecting the presence of the surrogate marker in the sample of bodily fluid, wherein said sensor responds to the surrogate marker by changing the resistance in each polymer resulting in a pattern change in the sensor array;
- (b) a processor for receiving the change in resistance, comparing the change in resistance with a previously measured change in resistance, and identifying the presence of the surrogate marker from the pattern change and the concentration of the surrogate marker from the amplitude.

11. The method according to claim 1, wherein the nanostructure-based assembly comprises at least one nanoparticle comprising a surrogate marker and a means for detecting a target analyte/biomarker, wherein the means for detecting the target analyte/biomarker is bound to the nanoparticle in such a way as to affect the release of the surrogate marker when in the presence of a target analyte/biomarker; wherein when the means for detecting the target analyte/biomarker is in the presence of the target analyte/biomarker, the surrogate marker is released for detection by the sensor technology.

12. A system useful in the detection of at least one target analyte/biomarker in a sample of bodily fluid collected *ex vivo* comprising a composition comprising a nanostructure-based assembly; and at least one sensor technology.

13. The system according to claim 12, wherein the nanostructure-based assembly comprises a nanoparticle, a surrogate marker, and a detecting means, wherein the detecting means can localize the nanostructure-based assembly to the target analyte/biomarker.

14. The system according to claim 13, wherein the nanoparticle comprises a hollow interior, a first end, a second end, and an end-cap, wherein the surrogate marker is located within the hollow interior, wherein the first end is open and the second end is closed, the first end being blocked with the end-cap to prevent the release of the surrogate marker, wherein a means for detecting the target analyte/biomarker is attached to the end-cap; wherein when the means for detecting the target analyte/biomarker is in the presence of the target analyte/biomarker, the end-cap is displaced from the first end to release the surrogate marker.

15. The system according to claim 14, wherein the means for detecting the target analyte/biomarker is selected from the group consisting of aptamers, antibodies, proteins, and receptor ligands.

16. The system according to claim 15, wherein the aptamer is capable of binding to the target analyte/biomarker selected from the group consisting of α II-spectrin breakdown products and protease-specific spectrin breakdown products.

17. The system according to claim 12, wherein the target analyte/biomarker is a nucleic acid, a protein, an illicit drug, an explosive, a toxin, a pharmaceutical, a carcinogen, a poison, an allergen, or an infectious agent.

18. The system according to claim 13, wherein the target analyte/biomarker is selected from the group consisting of acetaldehyde, acetone, ammonia, CO, chloroform, dichlorobenzene, diethylamine, hydrogen, isoprene, methanethiol, methylethylketone, O-toluidine, pentane sulfides and sulfides, H₂S, MES, and Me₂S.

19. The system according to claim 12, wherein the sample of bodily fluid is selected from the group consisting of: exhaled breath, blood, urine, bile, sweat, feces, semen, saliva, mucus, and cerebral spinal fluid.

20. The system according to claim 12, wherein the sensor technology is selected from the group consisting of surface-acoustic-wave sensors; fluid sensor technology; semiconductive gas sensors, mass spectrometers; IR, UV, visible and fluorescence spectrophotometers; conductive-polymer gas-sensors; aptamer biosensors; and amplifying fluorescent polymer sensors.

21. The system according to claim 13, wherein the sensor technology comprises:

- (a) a surface-acoustic wave (SAW) sensor capable of detecting the presence of the surrogate marker in the sample of bodily fluid, wherein the SAW sensor responds to the surrogate marker by a shift in the resonant frequency;
- (b) an oscillator circuit having the SAW sensor as an active feedback element;
- (c) a frequency counter in communication with said oscillator circuit to measure oscillation frequency which corresponds to resonant frequency of the SAW sensor; and
- (d) a processor for comparing the oscillation frequency with a previously measured oscillation frequency of the surrogate marker and determining presence and concentration of the surrogate marker therefrom.

22. The system according to claim 13, wherein the sensor technology comprises:

- (a) a sensor having an array of polymers capable of detecting the presence of the surrogate marker in the sample of bodily fluid, wherein said sensor responds to the surrogate marker by changing the resistance in each polymer resulting in a pattern change in the sensor array;
- (b) a processor for receiving the change in resistance, comparing the change in resistance with a previously measured change in resistance, and identifying the presence of the surrogate marker from the pattern change and the concentration of the surrogate marker from the amplitude.

23. The system according to claim 12, further comprising a reporting means.

24. The system according to claim 23, wherein the reporting means is linked to the sensor technology.